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SUPERSENSITIVE LINEAR PRESSURE TRANSDUCER

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a national stage application of PCT/US2011/042713, filed Jun. 30, 2011, and claims the benefit of priority to U.S. Provisional Patent Application Ser. No. 61/360,291, filed Jun. 30, 2010, titled SUPERSENSITIVE LINEAR PRESSURE TRANSDUCER, all of which are incorporated herein by reference.

FIELD OF THE INVENTION

Various aspects of the present invention pertain to pressure transducers and, in particular, to pressure transducers implantable within an animal airway, and to transducers including comb capacitors.

BACKGROUND OF THE INVENTION

Long-term mechanical ventilation incurs substantial morbidity, mortality, and costs (1% to 1.5% of the United States GDP). Because both premature and delayed ventilator weaning can cause harm, a weaning protocol that is both expeditious and safe is helpful. For these reasons, physicians are interested in an evidence-based approach to weaning from mechanical ventilation. One aspect of some embodiments of the present invention is to develop an implantable microsensor to measure pressure in the pleural space. This would permit quantification of, currently unmeasured elements of respiratory mechanics that can then be incorporated into a clinical management scheme to improve the outcome of patients on ventilator support. During ventilator support, direct pleural pressure monitoring combined with other available parameters will improve understanding of the relationship between a patient's inspiratory effort, lung compliance, airway resistance, and work of breathing. This information will be useful in narrowing the differential diagnosis and grading the severity of respiratory distress, thereby enabling the clinician to tailor ventilator settings to the individual patient.

Historically, the technique of mechanical ventilation has grown from being used temporarily during surgical procedures to being a mainstay of life support for the critically ill patient. It has been estimated that ICU care accounts for 20% to 34% of all hospital costs, 7% to 8% of total healthcare costs and 1% to 1.5% of the United States gross domestic product. Patients requiring long-term mechanical ventilation in the ICU consume approximately 50% of ICU resources, despite the fact that they represent less than 10% of all ICU patients. Short-term ventilation (<48-hrs) is associated with excellent survival and a relatively short (i.e. inexpensive) hospital stay. However, it is attainable in less than 25% of all ventilated patients, and accounts for a very small percentage of total ventilator days.

On the other hand, studies show that 11-40% of ventilated patients admitted to the medical ICU required more than 1 week of mechanical ventilator support, and only 40-50% of these patients were eventually weaned during the monitored period of these studies. The weaning process may require weeks to months of care, thus consuming enormous ICU resources. A ventilator-dependent ICU patient has an estimated cost that is eight times that of a patient on a general medical/surgical floor. Crude estimates put the nationwide cost of mechanical ventilation for the year 1995 in the range

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of \$30 billion, exclusive of physician costs and the costs associated with long-term post-ventilator care.

Premature extubation followed by reintubation is associated with a six-fold increase in mortality compared with patients who can tolerate extubation. On the other hand, the costs associated with prolonged mechanical ventilation are not trivial. A European survey of practices related to mechanical ventilation indicated that approximately 42% of a patient's time on a ventilator is spent in the process of weaning.

The traditional measurements of respiratory mechanics that are currently used clinically to predict weaning success are hampered by false positives and false negatives. This makes the physician's judgment the determining factor. For example, one of the predictive indices, the RSBI (rapid shallow breathing index) has a sensitivity of 65-96% and a specificity of 0-73%. The reason behind the suboptimal performance of these predictors is based on poor understanding of the direct "inspiratory effort" (i.e. intrapleural pressure). The inspiratory effort expended by patients with acute respiratory failure ranges from four to six times the normal value. If this level of effort is sustained indefinitely in critically ill patients, they are prone to develop inspiratory-muscle fatigue. With careful selection of MV settings, inspiratory effort (IE) can be reduced to the normal range.

However, eliminating IE entirely is not desirable because it causes deconditioning and atrophy of the respiratory muscles. Presently with the available parameters, it is difficult to precisely and directly measure IE (i.e. intrapleural pressure). Therefore, physicians cannot actively pursue a target IE in a given ventilated patient. In addition, to trigger the ventilator, the patient's IE first has to result in a negative airway pressure. The negative intrapleural pressure counters the lung's elastic recoil and airway conduit resistance in order to generate a negative airway pressure that is less than the ambient pressure. This airway pressure is measured by the ventilator, and should reach a set sensitivity target to trigger the ventilator to provide a full breath. If the patient's effort is insufficient to trigger the ventilator, then that effort is "wasted". The consequences of wasted IE's are not fully known, but they add an unnecessary burden in patients whose inspiratory muscles are already under stress.

From a pathophysiological standpoint, continuous direct intrapleural pressure monitoring by an implantable microsensor integrated with other non-invasive respiratory measurements (tidal volume and flow rate) will allow calculation of the compliance, airway resistance, and work of breathing in mechanically ventilated patients. Knowledge of the compliance or airway resistance will assist physicians in narrowing their differential diagnosis, while measurements of spontaneous work of breathing will allow for a better index of lung disease severity and weaning potential.

What is needed are inventive apparatus and methods for improved measurement of respiratory pressures, and also for variable capacitors with increased resolution. Various embodiments of the present invention achieve these improvements in novel and nonobvious ways.

SUMMARY OF THE INVENTION

One aspect of some embodiments pertains to the fabrication of an implantable capacitive pressure sensor using micro-electro-mechanical systems (MEMS) technology.

One aspect of the present invention pertains to a variable capacitor. One embodiment further includes a stator including a plurality of electrically conductive plates each spaced apart from one another, each of said plates being in a first